

## EFFICACY REVIEW

~~Confidential Business Information (CBI) is discussed in this review. Do not disclose CBI to third parties or to anyone lacking appropriate clearances.~~

**Product(s):** Hot Shot Sudden DeathJ Brand Mouse and Rat Killer and Purina Assault Mouse/Rat Pellets

**Date:** August 16, 2005

**EPA Reg No(s):** 8845-127, 67517-71

**DP Bar code(s):** D287929 and D287928

**Chemical Code:** Bromethalin 112802

**Formulation(s):** Bromethalin Baits (Pellets)

**Purpose for Review:** The purpose for this review is to determine if the previously submitted efficacy tests dated June 21, 1990, December 7, 1992, and April 16, 1994, are acceptable for reregistration of the above named products.

**MRID No(s):** **435100-01C** Dickerson, C. W. June 21, 1990. Efficacy Testing of a Pelleted Rodenticide Bait in Wild House Mice. Purina Mills, Inc. Unpublished Report. OPP Designation 1.210. Experiment #62-769. 73pp.

**435100-02C** Dickerson, C. W. June 21, 1990. Efficacy Testing of a Pelleted Rodenticide Bait in Wild House Mice. Purina Mills, Inc. Unpublished Report. Experiment #62-770. 73pp.

**435100-03C** Dickerson, C. W. December 7, 1992. Efficacy Testing of a Pelleted Rodenticide Bait in Wild Norway Rats. Purina Mills, Inc. Unpublished Report. Experiment #62-884. 70pp.

**435100-04C** Dickerson, C. W. April 16, 1994. Efficacy Testing of a Pellet Rodenticide for Wild Roof Rats. Purina Mills, Inc. Unpublished Report. Experiment #62-953. 47pp.

**435319-01C** Dickerson, C. W. April 16, 1994. Efficacy Testing of a Pellet Rodenticide for Wild Roof Rats. Purina Mills, Inc. Unpublished Report. Experiment #62-952. 46pp.

\*Inert ingredient information may be entitled to confidential treatment\*

**Good Laboratory Practices:** Yes

**Branch Chief:** Meredith Laws

**Team Leader:** John Hebert, Product Manager 07

**IRB Reviewer:** Geraldine R. McCann, Biologist

**BACKGROUND:** B. Jacobs states: "This product is claimed to be formulated identically to Purina's 602-358 (67517-72), which in turn is identical to 602-315 (67517-69). The formulation used in all of these products contains [REDACTED]  
[REDACTED]  
[REDACTED] EPA permits the addition of [REDACTED] to rodenticide baits if it can be shown that the baits would be expected to perform effectively against target species. As the protective value of [REDACTED] in baits at concentrations which rodents will accept has not been shown for very young children or non-target animals, EPA does not permit label statements which imply that [REDACTED] or that usual protective measures can be compromised if the bait used contains [REDACTED]. Factual declarations that [REDACTED] is in the product are permitted as long as they are relatively inconspicuous. The laboratory efficacy studies were run in 1990, 1992, and 1993, with wild-type Norway rats, roof rats, and house mice. It is unusual, but desirable, for a company not only to submit data on wild-type Norway rats and house mice but also to include roof rats studies as well. These trials were conducted in Purina Mill's own facility in Bridgeton, MO. Some of the study reports were submitted previously for other products."

"The efficacy data guidelines used to screen the bait for effectiveness for these products are OPP 1.209 and 1.210. This review will evaluate the results of the studies and determine if the data are still acceptable."

Some general Bromethalin background: "When Bromethalin was being considered for initial registration, we generalized from results generated with warfarin-resistant rodents to allow claims of effectiveness against anticoagulant rodenticides. This was not done for the second-generation anticoagulants brodifacoum and bromadiolone because these agents are themselves anticoagulants. We permitted the generalization in bromethalin's case because (1.) Bromethalin is not an anticoagulant, (2.) there was evidence available that rodents resistant to warfarin were also resistant to other first-generation anticoagulants, (3.) evidence of mild resistance to some second-generation materials had been reported for some species, and (4.) there was no reason to believe that anticoagulant resistance would afford rodents any immunity to the effects of Bromethalin." (B. Jacobs, page 11, March 21, 1995, Review for 67517-69, Jacket 1 of 2).

## **Review of Data:**

### **DISCUSSION:**

With the EPA laboratory efficacy protocols 1.209 (for rats) and 1.210 (for mice), the bait exposure periods are 2 days in all the efficacy studies for these products. Purina used individually caged mice rather than unisex groupings of 5 or 10 mice each. Both procedures are acceptable. Trials within species were run concurrently.

In his review of the above named efficacy studies, B. Jacobs stated: “Both test methods call for at least one group of 20 animals (10 males and 10 females) being exposed to toxic bait in a choice situation with OPP’s standard challenge diet being provide as the alternative and for a similarly constituted control group that is offered only challenge diet. Rodents were maintained under test conditions on Purina Rat Chow for 3 days prior to introduction of the bait and challenge diet. After 2 days, bait was removed from cages of survivors and control group animals, but consumption of challenge diet was monitored for 6 additional days. (The protocols call for a minimum of 5 days of post treatment monitoring).”

“The data indicate that the performance criterion of 90% mortality was exceeded in all tests for all three species. In fact, there were no survivors among the 40, 20, and 40 bait-exposed Norway rats, roof rats, and house mice, respectively, that were exposed to test baits.” (Table 1.) Mice died more quickly with nearly a third of exposed subjects expiring on the first day of bait exposure. “In contrast, roof rats took the longest to die, with only 10% dying on Day 1 and 15% surviving Day 2. All Norway rats died within 2 days, with 85% surviving until Day 2. These findings are consistent the results of earlier tests of Bromethalin which showed that roof rats are a bit less sensitive to this chemical than are the other two major commensal species in the U.S. In order to control roof rats effectively with Bromethalin baits, the concentration of the toxicant had to be increased from 0.005% to 0.01%.

“The most remarkable findings in these trials were the extremely high bait acceptance figures for most individuals of all species. The high bait acceptance figures could have been due to the use of an extremely palatable bait or to the use of bad quality challenge diet. High acceptance scores can result from the use of bad challenge diet, but there is no way to determine whether any or all of Purina’s challenge diet batches were bad.”

**Table 1. Results of the Studies submitted to support Assault Mouse/Rat Pellets (67517-71) and Hot Shot Sudden Death Brand Rat and Mouse Killer 1 (8845-127) for Reregistration.**

Test MRID Numbers	Subject #s	Sex	Toxic Bait Eaten (g)	OPP Diet Eaten (g)	Bait Acceptance Rate (%)	Mortality Results (%)	Days to Death
435100-03	20	B	162.1	15.8	91.1	100	1-2
435100-04	20	B	116.4	33.6	77.6-81.4	100	1-7
435319-01	20	B	119.7	18.7	86.5-89.3	100	1-5
435100-01	20	B	18.1	2.6	87.4-92.1	100	1-2
435100-02	20	B	16.9	2.1	88.9-88.6	100	1-2

**Efficacy Comments**

1. The efficacy reports submitted for this product reregistration have been found acceptable.
2. No verification could be determined for the freshness of the challenge diet used in the bioassays. This may have been the reason for the high consumption rates of toxic baits in the trials.
3. All of the studies were done with the minimum of animals without repeating the test. As called for in the guidelines, one more group of animals should have been used to verify the results. The additional test results must be submitted in future study submissions.

**Conclusion(s):** I agree the W. Jacobs conclusions from his May 17<sup>h</sup>, 1995, review that AThe efficacy data submitted to support the claims made for this product are acceptable.@